K002620 NOV 16 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (21CFR 807.92)

I. DATE PREPARED: August 28, 2000

II. SUBMITTER:
OraMetrix, Inc.
12740 Hillcrest Road Suite 100
Dallas, Texas 75230

III. CONTACT PERSON:
Nancy Butcher
Director of Quality Assurance & Regulatory Affairs
OraMetrix, Inc.
(972)-728-5534

IV. DEVICE NAME:
Trade/Proprietary Name: SureSmile™ System
Common Name: 3-D Intraoral Camera and Accessories

V. DEVICE CLASSIFICATION
Class I under 21 CFR 872.6640.

VI. PREDICATE DEVICE:
Spectra Vu 1000 Series Intraoral Camera and Accessories
K984332
Class I
Decision Date: 04/29/99

VII. SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

OraMetrix, Inc. concludes that the intended use for the OraMetrix SureSmile™ System is the same as that of the predicate device, and that the technological characteristics demonstrate that they are equivalent to the predicate device. A comparison of the technological characteristics of the predicate and legally marketed devices available has been performed.

Thus, this premarket notification has demonstrated substantial equivalence.

VIII. DEVICE DESCRIPTION AND INTENDED USE:

The OraMetrix SureSmile System is a complete image management system capable of acquisition, transmission, archive, display and print of patient images and demographic information. Its purpose is to facilitate these operations utilizing shared data to promote the availability of information locally, remotely, and at other facilities other than which it was acquired.

The process begins by using the OraScanner to obtain a three-dimensional digital image of the dentition to provide the orthodontist a 3-D view of the teeth. These images may be integrated with other patient records to establish a three-dimensional treatment objective. This treatment objective is then used to design a custom appliance system, prescribed by the orthodontist, which is specific to each patient's needs. Follow up scans using the OraScanner allow the orthodontist to precisely monitor patient progress through the entire treatment.

Systems are configured to meet the customer's needs. Fully integrated systems could enable orthodontist to utilize speech recognition.

IX. THE DEVICE

The general hardware configuration of the systems may contain the following major components: Connectivity and comparability are evaluated and ensured via the integration test processes internal to OraMetrix, Inc.

-SureSmile™ OraScanner
-Monitors
-Central Processing Units (CPU, memory, disks, microphone, speakers)
-Film and Document scanners
-Digital camera
-CD-ROM writer / reader
-Optical Disk Libraries
-RAID array
-DLT Tape Libraries
-9840 Tape Libraries
-CD-R writer / reader
-DVD-R writer / reader

X. INDICATION FOR USE

The SureSmile™ System is used to provide a total orthodontic care solution to orthodontists with an image acquisition and viewing technology that delivers value throughout the entire care cycle; including record collection, treatment planning, treatment delivery, monitoring of care and patient communication.

This treatment objective is then used to design a custom appliance system, prescribed by the orthodontist, which is specific to each patient's needs. The result is a comprehensive care solution that addresses many problems that orthodontists face with patient care.

The OraScanner is not intended for use as an operative device and is not manufactured to be sterile.

XI. SAFETY INFORMATION:

The System has limited patient contact and is utilized only by trained professionals. The scanner tips are removable to be sterilized between uses. The hand held unit has been designed to be wiped clean with commercially available disinfectant between uses. Additional trained professionals allowing sufficient review to afford identification and intervention in the event of a malfunction have evaluated the output of the device.

Selection of the specific components of the system has been made to allow the system to remain cost effective and consistent with current technology through the substitution of components as technology develops. By retaining criteria for the substitution of components, any concerns about safety or efficacy and substantial equivalence can be satisfactorily met by a determination that the component substitution is not a significant change in the system. This is consistent with the existing Agency guidance.

XII. CONCLUSION [21 CFR: 807.92(b)(3)]

OraMetrix, Inc. believes sufficient information is included to reach a determination of substantial equivalence. We conclude that the subject device is as safe and effective including the component and accessory devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2000

Ms. Nancy Butcher
Director of Quality Assurance & Regulatory Affairs
ORA Metrix, Incorporated
12740 Hillcrest Road, Suite 100
Dallas, Texas 75230

Re: K002620
Trade Name: SureSmile System
Regulatory Class: I
Product Code: EIA
Dated: August 23, 2000
Received: August 23, 2000

Dear Ms. Butcher:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002620

Device Name: SureSmile™ System

Indications for Use:

The SureSmile™ System is used to provide a total orthodontic care solution to orthodontists with an image acquisition and viewing technology that delivers value throughout the entire care cycle; including record collection, treatment planning, treatment delivery, monitoring of care and patient communication.
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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over the Counter Use _____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002620